STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR MEDICAL SERVICES

Office of Pharmacy Services Prior Authorization Criteria

DAKLINZA® (daclatasvir)

Effective 2/5/2016

Prior Authorization Request Form
Prior Authorization Continuation Request Form
Patient Consent Form
Preferred HepC Regimens (Attachment A)

Daklinza is a hepatitis C virus (HCV) NS5A inhibitor indicated for use with sofosbuvir, with or without ribavirin, for the treatment of chronic HCV genotype 1 or 3 infection.

Criteria for Approval

1) All documentation must be fully completed, including the patient consent form. A fibrosis score substantiated by a validated evidence-based method must be reported when requesting prior authorization; **AND**

2) Patient must have a documented **fibrosis level ≥ F3 without cirrhosis**; **AND**

3) Patient must be eighteen (18) years of age or older; **AND**

4) Daclatasvir must be prescribed by, or in conjunction with, a board certified gastroenterologist, hepatologist or infectious disease physician; **AND**

5) Patient must be diagnosed with chronic Hepatitis C Genotype 1 or 3; **AND**

6) Patient must also have a concurrent prescription for sofosbuvir; **AND**

7) Patient has abstained from the use of illicit drugs and alcohol for a minimum of three (3) months, as indicated by their signature on the Patient Consent form; **AND**

8) Patient must agree to complete the full regimen and the patient and the provider must agree that an SVR12 and SVR24 will be collected and submitted to WV Medicaid to verify therapy success.

Duration of Approval

1) A list of accepted regimens and treatment duration for chronic Hepatitis C therapy may be found in Attachment A.

2) Initial approval is for 6 weeks and requires submission of the starting HCV RNA level.

3) Continued coverage after week 6 depends upon receipt of an HCV RNA level at treatment week 4 (TW4), documentation of patient compliance, continued abstinence and an HCV RNA < 25 IU/ml. **Failure to obtain and report a treatment week 4 HCV RNA load will result in denial of further coverage.**

Criteria for Denial

1) Requests submitted with incomplete documentation will be denied.

2) Failure to report a fibrosis score.

3) Evidence exists that the patient has abused any illicit substance or alcohol in the past three (3) months.

4) Patient has severe renal impairment (eGFR < 30 mL/min/1.73m2) or end stage renal disease (ESRD) requiring hemodialysis.

5) Patient has been previously treated with **daclatasvir + sofosbuvir.**

6) Patient is taking a concomitant medication that has a significant clinical interaction with sofosbuvir:
    a. tipranavir/ritonavir
    b. rifampin, rifabutin, rifapentine
    c. carbamazepine, phenytoin, phenobarbital, oxcarbazepine
    d. St. John's wort

7) **Requests for continuation of coverage will be denied if the patient has an HCV RNA level >25 IU/ml OR if the prescriber has not submitted or has not obtained a viral load at treatment week 4.**

Additional Considerations

1) It is highly recommended that the patient vaccinated against Hepatitis A and Hepatitis B

2) Sofosbuvir is a nucleotide analog NS5B polymerase inhibitor; Daclatasvir is an inhibitor of the hepatitis C virus NS5A protein.

3) For HCV/HIV co-infections all requests must be reviewed for drug-drug interactions prior to approval. Please submit a list of the patient's current HIV regimen along with your request for coverage of Daklinza.

4) Coverage shall be for one successful course of therapy in a lifetime. Success of therapy shall be judged by undetectable SVR12 and SVR24 HCV RNA levels. If RNA levels have not been submitted, then it will be assumed that therapy was successful. Re-infection will not be covered. Exceptions may be allowed on a case-by-case basis.

5) Lost or stolen medication replacement request will not be authorized.

References

1) FDA News Release. FDA approves new treatment for chronic hepatitis C genotype 3 infections. July 24, 2015. http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm455888.htm
2) Daklinza [package insert]. Bristol-Myers Squibb Company, Feb 2016.
3) Sovaldi [package insert]. Foster City, CA; Gilead, August 2015.